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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,865	07/31/2001	Gideon Strassmann	116-039	2422

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EXAMINER	
LUKTON, DAVID	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/918,865	STRASSMANN ET AL.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 8-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicants election of Group 4 with traverse is acknowledged (claims 6, 7, 18, drawn to a method, limited to G1). Applicants have traversed by arguing that the 35 USC §112, second paragraph statute bars restriction. However, this is not true. Moreover, by electing method claims, applicants have voluntarily relinquished the opportunity to have the composition claims rejoined with the method claims. The restriction requirement is maintained.

Claims 1-5, 8-17 are withdrawn from consideration

✧

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 18 is drawn to a method of "prophylaxis or treatment". Since no diseases are specified, one can assume that applicants intend to encompass all diseases. However, there is no evidence that there exists even one disease which will yield to the compounds

of claim 3. The reality in pharmacology is that even when one has a compound with a proven in vitro activity, and a vision as to how that *in vitro* activity might be harnessed to produce a therapeutically effective drug, the hurdles which must be overcome in realizing that vision are enormous, and indeed, usually insurmountable. Often the compound is not as active *in vitro* as hoped, or it never reaches the target site in sufficient quantity, or it is too readily metabolized, or the biochemical process which is either inhibited or stimulated by the compound is not critical to the etiology or manifestations of the disease. Or perhaps the compound is not effective at non-toxic levels, a concern which is relevant given the toxicity of tellurium. Thus, for a variety of reasons, a compound which is effective in vitro is often therapeutically ineffective.

But when one merely selects a compound at random, and has no sense of what activity it might exhibit, one can have no hope of successfully treating even one disease, to say nothing of all diseases. And applicants have gone even a step further by asserting that they can prevent any and all diseases ("prophylaxis"). Clearly, at the very least, "undue experimentation" would be required to practice the claimed invention. It is suggested that the following terms be deleted from claim 18: "prophylaxis", "treatment" and "therapeutically".

✧

Claims 6 and 18 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for

failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Each of claims 6 and 18 is dependent on a non-elected claim.
- Claim 18 is indefinite as to the "prophylaxis or treatment" that may be intended.

✧

The following is a quotation of 35 USC. 103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 6, 7, 18 are rejected under 35 U.S.C. §103 as being unpatentable over Sredni (USP 5,475,030).

Sredni discloses (col 5, line 51+) various tellurium compounds that are asserted to be useful for treatment of cancer, immune deficiencies, autoimmune diseases and infectious

diseases. Sredni does not disclose that animals which are afflicted with one or more of the foregoing diseases can experience weight loss. Hoever, it is known to veterinarians of ordinary skill that animals (including birds) which are stricken with cancer, immune deficiencies, autoimmune diseases or infectious diseases will often suffer a weight loss. Thus, it would have been obvious to one of ordinary skill at the time of the invention that if one of the tellurium compounds of Sredni is administered to an underweight bird that is stricken with cancer, an immune deficiency, an autoimmune disease or an infectious disease, the bird will gain weight if the compounds are effective to eradicate the bird's illness as asserted in the '030 patent.

✧

Claims 6, 7, 18 are rejected under 35 U.S.C. §103 as being unpatentable over Sredni (USP 5,126,149) or Albeck (USP 4,761,490) in view of Lowenthal (USP 6,642,032).

Sredni and Albeck both teach that tellurium compounds are effective to promote production of lymphokines. Such lymphokines include (col 1, line 42, Albeck) *gamma* interferon. Neither of Sredni or Albeck disclose that an effect of increasing production of *gamma* interferon is to promote weight gain in birds. Lowenthal discloses that *gamma* interferon promotes weight gain in birds. Thus, it would have been obvious to one of ordinary skill that administering an organotellurium compound to a bird will result in weight gain.

Applicants' data on page 15 (specification) is noted. Consider also that the claims

encompass the following four categories of invention:

(a) juvenile birds in a rapid growth phase, wherein the birds are healthy;

(b) juvenile birds in a rapid growth phase, wherein the birds are unhealthy;

(c) fully grown adult birds that are healthy;

(d) fully grown adult birds that are unhealthy.

If one stipulates that the data on page 15 qualify as "unexpected", the data would serve to render novel only the first of the four categories of invention. This ground of rejection primarily targets categories (b), (c) and (d), for which there are no "unexpected results".

Thus, the claims are rendered obvious.

✧

Claims 6, 7, 18 are rejected under 35 U.S.C. §103 as being unpatentable over Sredni (USP 4,929,739)

Sredni discloses that complexes of tellurium and selenium are effective to treat cancer and immunodeficiency. Sredni does not disclose that animals afflicted with cancer or immunodeficiency often suffer weight loss. However, this is known to the veterinarian of ordinary skill. Moreoever, such weight loss is going to be inevitable for animals that must hunt for food. Thus, the veterinarian of ordinary skill would have expected that by administering the disclosed complexes of tellurium and selenium to an underweight animal

(e.g., a bird) that is afflicted with cancer or immunodeficiency, the health of the animal will be restored, and normal weight realized.

✧

Claims 6, 7, 18 are rejected under 35 U.S.C. §103 as being unpatentable over Sredni (USP 4,929,739) in view of Lowenthal (USP 6,642,032).

Sredni discloses that complexes of selenium and tellurium are effective to promote production of lymphokines. Such lymphokines would include *gamma* interferon. Sredni does not disclose that an effect of increasing production of lymphokines is to promote weight gain in birds. Lowenthal discloses that a lymphokine (*gamma* interferon) promotes weight gain in birds. Thus, it would have been obvious to one of ordinary skill that administering an organotellurium or organoselenium compound to a bird will result in weight gain.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600

✺

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.